

### **REMARKS**

The Applicants respectfully request reconsideration of the application in view of the remarks made herein.

#### ***Formal Matters***

Claims 1 and 6 have been amended to specify "providing a biopolymer array production system comprising: a substrate station configured to retain a biopolymer array substrate; a movable printhead system comprising a first printhead assembly; and a computer processor configured to control said movable printhead system to form a biopolymer array on a substrate retained in said substrate station" and "replacing said first printhead assembly with a second printhead assembly, wherein said first and second printhead assemblies are different". Support for these amendments can be found e.g., in Claim 27, and throughout the specification, see, e.g., pages 3-5, paragraphs [0007]-[0011] and pages 22-27, paragraphs [0056]-[0065].

Claims 1 and 6 have also been amended to specify that the printhead assembly comprise "one or more nozzle plates". Support for this amendment can be found throughout the specification, see, e.g., page 21, paragraph [0050].'

Claim 21 has been amended to specify "in packaged combination with instructions for use with said computer-readable medium". Support for this amendment can be found throughout the specification, see e.g., pages 33-35, paragraphs [0082]-[0086].

Claim 27 is cancelled without prejudice.

As the above amendments introduce no new matter, entry of these amendments by the Examiner is respectfully requested.

***Claim Rejections – 35 USC §112-First Paragraph, Enablement***

Claims 1-10, 12-17 and 21-27 are rejected under 35 U.S.C. §112, first paragraph for allegedly failing to satisfy the enablement requirement. Specifically, the Examiner asserts that “[t]he printhead control model, printhead control software, device capable of reading electronic media, user interface, and other structural components are critical of reading electronic media, user interface, and other structural components are critical or essential to the practice of the invention, but not included in the claim(s) is not enabled by the disclosure”.

In making this rejection, the Examiner asserts that although “the present claims are directed to a method involving biopolymer array production system”, “[t]here is no step of providing a production system”. As such, the Examiner suggests that “the first step should be providing such production system comprising the required components to allow for the method steps to be performed”. Furthermore, the Examiner also asserts that “the claim does not structural define what is considered a biopolymer array production device” and that “[i]t is unclear how the method is performed without providing for all the structural components”.

In considering what constitutes an enabling disclosure for a claimed invention, the Federal Circuit has repeatedly held that a specification meets this requirement if it teaches those skilled in the art how to make and use the full scope of the claimed invention without “undue experimentation” (see, e.g., *In re Wright*, 999 F.2d 1557, 1561, 27 USPQ2d 1510, 1513 (Fed. Cir. 1993)). The “undue experimentation” test has not been interpreted to mean that everything necessary to practice the invention must be disclosed in the specification. Indeed, it is often preferable to exclude aspects of the claimed invention that are well-known in the art (see, e.g., *In re Buchner*, 929 F.2d 660, 661, 18 USPQ2d 1331, 1332 (Fed. Cir. 1991)).

In brief, what is necessary to fulfill the enablement requirement of 35 U.S.C. §112, first paragraph, is that one skilled in the art be able to practice the claimed invention (taking into consideration the level of knowledge and skill in the art). Furthermore, the scope of enablement must only bear a “reasonable correlation” to

the scope of the claims (see, e.g., *In re Fisher*, 427 F.2d 833, 839, 166 USPQ 18, 24 (CCPA 1970)).

In view of the requirements for enabling a claimed invention as described above, the Applicants submit that the specification teaches those of skill in the art how to make and use the full scope of the claimed invention without “undue experimentation” and as such fully enables the invention as claimed.

However, solely to expedite prosecution and without agreeing to the correctness of this rejection, Applicants have amended claims 1 and 6 to describe the structural features of the biopolymer array production system specifying the element of “providing a biopolymer array production system comprising: a substrate station configured to retain a biopolymer array substrate; a movable printhead system comprising a first printhead assembly; and a computer processor configured to control said movable printhead system to form a biopolymer array on a substrate retained in said substrate station” and to clarify that the method of producing a biopolymer array includes the steps of “replacing said first printhead assembly with a second printhead assembly, wherein said first and said second printhead assemblies are different” and “entering, by an operator using an operator input device or electronically reading from electronic media, printhead-related data into said computer processor”.

As such, Applicants submit that the claims adequately define the structural components of the biopolymer array production system in order to perform the claimed method and as such, the claims recite subject matter which is sufficiently enabled by the present disclosure. Therefore, Applicants submit that the invention as claimed, satisfies the enablement requirement and respectfully request withdrawal of this rejection.

***Claim Rejections – 35 USC §112-First Paragraph, Written Description***

Claims 1-10, 12-17 and 21-27 are rejected under 35 U.S.C. §112, first paragraph for allegedly failing to satisfy the written description requirement.

Specifically, the Examiner asserts that "the claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention".

In making this rejection, the Examiner alleges that "the invention as claimed is not disclosed in the specification". To support this assertion, the Examiner cites identical reasons as noted above for the rejection under 35 USC §112-First Paragraph, Enablement.

As noted above, Claims 1 and 6 have been amended to describe the structural features of the biopolymer array production system specifying the element of "providing a biopolymer array production system comprising: a substrate station configured to retain a biopolymer array substrate; a movable printhead system comprising a first printhead assembly; and a computer processor configured to control said movable printhead system to form a biopolymer array on a substrate retained in said substrate station" and to clarify that the method of producing a biopolymer array includes the steps of "replacing said first printhead assembly with a second printhead assembly, wherein said first and said second printhead assemblies are different" and "entering, by an operator using an operator input device or electronically reading from electronic media, printhead-related data into said computer processor".

As such, Applicants submit that the claims adequately define the structural components of the biopolymer array production system in order to perform the claimed method and as such, the claims recite subject matter which is sufficiently described by the present disclosure. Therefore, Applicants submit that the claimed invention sufficiently satisfies the written description requirement and respectfully request withdrawal of this rejection.

***Claim Rejections – 35 USC §112, Second Paragraph***

Claims 1, 4, 6, 8, 9, 21 and 24 are rejected under 35 U.S.C. §112, second paragraph as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

With respect to claims 1, 4, 6, 9 and 24, the Examiner asserts that the claims are unclear because the claims allegedly do not possess sufficient structural definition.

As noted above, Applicants submit that Claims 1 and 6 have been amended to define structural components of the biopolymer array production system as suggested by the Examiner. Therefore, Applicants submit that Claims 1, 4, 6, 9 and 24 are sufficiently clear and are not indefinite.

With respect to Claim 21, the Examiner alleges that Claim 21 is unclear because the phrase “use with the same” is unclear.

In response, Applicants have amended Claim 21 to specify “in packaged combination with instructions for use with an array fabrication apparatus”. In view of this amendment, Applicants submit that Claim 21 is sufficiently clear and is not indefinite.

With respect to Claim 8, the Examiner alleges that Claim 8 is directed to new matter. Specifically, the Examiner asserts that “[t]he specification does not disclose a printhead assembly as including electronic media” and that “[p]aragraphs 42-44 do not support the amendment as asserted by applicant”.

Applicants respectfully disagree with the Examiner. Contrary to the assertions of the Examiner, the specification as originally filed fully supports the elements of “wherein said printhead assembly comprises electronic media, and wherein said printhead-related data is read from said electronic media”. As described on page 5, paragraphs [0010]-[0011], “memory files and programming module(s) may be

provided to enable simple plug-and-play operability in reconfiguring the system for use". As such, the claimed printhead assembly may comprise electronic media such that it may be employed with "plug-and-play operability in reconfiguring the system for use". Applicants submit that one of ordinary skill in the art would recognize the phrase and definition of "plug-and-play" and that a printhead assembly which employs "plug-and-play operability" would include the electronic media. Therefore, Applicants submit that the element of "wherein said printhead assembly comprises electronic media" is fully supported by the specification coupled with knowledge possessed by one of ordinary skill in the art. As such, Claim 8 does not introduce new matter into the instant application.

In view of the amendments to the claims and the remarks made above, Applicants submit that Claims 1, 4, 6, 8, 9, 21 and 24 are sufficiently clear and are not indefinite and respectfully request withdrawal of this rejection.

***Claim Rejections – 35 USC §102 – Shchegrova, et al.***

Claims 1-10, 12-17, 21-22 and 27 are rejected under 35 U.S.C. §102(e) as being anticipated by Shchegrova et al. (U.S. 2003/0143329).

Specifically, the Examiner alleges that Shchegrova et al. discloses a "method, apparatus, and computer program products useful in fabricating chemical biopolymer arrays" which anticipates the claimed invention.

For a rejection of claims under §102 to be properly founded, the Office must establish that a single prior art reference either expressly or inherently discloses each and every element of the claimed invention. *See, e.g. Hybritech Inc. v. Monoclonal Antibodies, Inc.*, 231 USPQ 81 (Fed. Cir. 1986), *cert. denied*, 480 U.S. 947 (1987); and *Verdegaal Bros. v. Union Oil Co. of California*, 2 USPQ2d 1051, 1053 (Fed. Cir. 1987). In *Scripps Clinic & Research Found. v. Genentech, Inc.*, 18 USPQ2d 1001 (Fed. Cir. 1991), the Federal Circuit held that:

**"Invalidity for anticipation requires that all of the elements and limitations of the claim are found within a single prior art reference.... There must be no difference between the claimed invention and the reference disclosure, as viewed by a person of ordinary skill in the field of the invention."**  
*Id.* at 1010.

Anticipation cannot be found, therefore, unless a cited reference discloses all of the elements, features or limitations of the presently claimed invention. Applicants respectfully submit that Shchegrova et al. fails to recite all of the elements of claims 1-10, 12-17, 21-22 and 27.

In making this rejection, the Examiner alleges that Applicants' assertion that "selecting a frame as specified in Shchegrova is not the same as selecting a printhead assembly" is merely a "matter of interpretation of what can be considered equivalent to the step of 'selecting a printhead assembly' and that "the mere choice of an operator to use a device such as disclose by Shchegrova will satisfy the step of selecting a printhead assembly", as claimed.

Applicants respectfully disagree with the assertions of the Examiner. However, solely to expedite prosecution of the subject application, Claims 1 and 6 have been amended to specify "replacing said first printhead assembly with a second printhead assembly, wherein said first and second printhead assemblies are different and wherein said printhead assembly comprises multiple printheads and one or more nozzle plates, wherein each of said printheads comprises one or more wells, wherein each of said one or more wells comprises one or more nozzle regions, wherein each of said one or more nozzle regions comprises one or more nozzle rows and wherein each of said one or more nozzle rows comprises multiple nozzle orifices". As such, preparing a biopolymer array production system for operation as claimed, requires the step of replacing a first printhead assembly on the biopolymer array production system with a second, different printhead assembly.

Applicants submit that Shchegrova fails to teach this element of the claims. In contrast, Shchegrova teaches selecting a frame on a printhead in order to determine a set of best “non-error” dispensers. A frame as taught in Shchegrova, is “a series of dispensers which can simultaneously move along selected paths”. Therefore, selecting a “frame” as defined by Shchegrova, is selecting a subset of nozzles on a particular printhead. Shchegrova does not teach “replacing said first printhead assembly with a second printhead assembly” on a biopolymer production system.

Therefore, since Shchegrova fails to teach the element of “replacing said first printhead assembly with a second printhead assembly”, Shchegrova fails to teach each and every element of the claimed invention.

As such, Claims 1-10, 12-17, 21-22 and 27 are not anticipated under 35 U.S.C. §102 by Shchegrova, et al. Applicants thus respectfully request withdrawal of this rejection.

***Claim Rejections – 35 USC §102 – Ganz, et al.***

Claims 1-10, 12-17, 22-27 are rejected under 35 U.S.C. §102(e) as being anticipated by Ganz et al. (U.S. Patent No. 6,979,425).

Specifically, the Examiner alleges that Ganz et al. discloses a “high capacity microarrayer (DNA printer) for spotting solution onto slides in an automated microarray dispensing device” and that “the operator or program inputs/reads data to select which printhead and specific number of nozzles to use” which allegedly anticipates the claimed invention.

As noted above, Claims 1 and 6 have been amended to specify the step of “replacing said first printhead assembly with a second printhead assembly, wherein said first and second printhead assemblies are different and wherein said printhead assembly comprises multiple printheads and one or more nozzle plates, wherein each of said printheads comprises one or more wells, wherein each of said one or more wells comprises one or more nozzle regions, wherein each of said one or more



nozzle regions comprises one or more nozzle rows and wherein each of said one or more nozzle rows comprises multiple nozzle orifices". As such, preparing a biopolymer array production system for operation as claimed, requires the step of replacing a first printhead assembly on the biopolymer array production system with a second, different printhead assembly.

Applicants submit that Ganz fails to teach this element of the claims. In contrast, Ganz teaches a microarray dispensing device which allows an operator "to rework a spot based on a computer determination of pass or fail" and "the rework decision is made automatically by the computer based on whether or not the spot has passed or failed". Therefore, Ganz is directed to a device which allows an operator to select a subset of nozzles on a particular printhead of the microarray device which an operator or computer program has determined to have "failed". Ganz does not teach "replacing said first printhead assembly with a second printhead assembly" on a biopolymer production system, as claimed.

Therefore, since Ganz fails to teach the element of "replacing said first printhead assembly with a second printhead assembly", Ganz fails to teach each and every element of the claimed invention.

As such, Claims 1-10, 12-17, 22-27 are not anticipated under 35 U.S.C. §102 by Ganz, et al. Applicants thus respectfully request withdrawal of this rejection.

#### ***Claim Rejections – 35 USC §103***

Claims 21 is rejected under 35 U.S.C. §103(a) as being unpatentable over Ganz et al. (U.S. Patent No. 6,979,425).

In order to meet its burden in establishing a rejection under 35 U.S.C. § 103 the Office must first demonstrate that the combined prior art references teach or suggest all the claimed limitations. See *Pharmastem Therapeutics, Inc. v. Viacell, Inc.*, 491 F.3d 1342 (Fed. Cir. 2007) ("the burden falls on the patent challenger to

show by clear and convincing evidence that a person of ordinary skill in the art would have had reason to attempt to make [every element of] the composition or device, or carry out the [entire] claimed process, and would have had a reasonable expectation of success in doing so," (*citing KSR Int'l Co. v. Teleflex Inc.*, 127 S. Ct. 1727, 1740 (2007))); and see *Omegaflex, Inc. v. Parker-Hannifin Corp.*, 243 Fed. Appx. 592, 595 (Fed. Cir. 2007) ("[t]he Supreme Court recently explained that 'a patent composed of several elements is not proved obvious merely by demonstrating that each of its elements was, independently, known in the prior art,'" (*citing KSR Int'l Co.* at 1741)); and see *Dystar Textilfarben GmbH v. C.H. Patrick Co.*, 464 F.3d 1356, 1360 (Fed. Cir. 2006) ("[o]nce all claim limitations are found in a number of prior art references, the factfinder must determine '[w]hat the prior art teaches, whether it teaches away from the claimed invention, and whether it motivates a combination of teachings from different references,'" (*citing In re Fulton*, 391 F.3d 1195, 1199-1200 (Fed. Cir. 2004))).

In making this rejection, the Examiner asserts that Ganz teaches all of the elements of the claimed invention as recited in Claim 21. The Examiner acknowledges that Ganz fails to teach "the device is packaged with instructions". However, the Examiner asserts that this is not of patentable merit because "[i]t would have been obvious to one of ordinary skill in the art at the time of the invention to recognize that the device of Ganz, et al. would be accompanied with an operational/instruction manual to provide usage information to allow for proper operation of the device".

As noted above, Claim 1 has been amended to specify the step of "replacing said first printhead assembly with a second printhead assembly, wherein said first and second printhead assemblies are different". Claim 21 depends from Claim 1 and as such, includes this element. As described above, Applicants submit that Ganz fails to teach this element of the claims. Furthermore, Applicants submit that Ganz fails to suggest this element. Indeed, Ganz is specifically directed to a device which allows an operator to select and "rework" a subset of nozzles on a particular printhead of the microarray device which an operator or computer program has

determined to have "failed" and is completely silent to replacing a "first printhead assembly with a second printhead assembly" as claimed.

Therefore, since Ganz, et al. fails to teach or suggest the element of "replacing said first printhead assembly with a second printhead assembly", Ganz fails to teach each and every element of the claimed invention. As such, Claim 21 is not obvious under 35 U.S.C. §103(a) over Ganz, et al.

Applicants thus respectfully request withdrawal of this rejection.

**CONCLUSION**

In view of the amendments and remarks above, Applicants submit that all of the claims are in condition for allowance, which action is requested. If the Office finds that a telephone conference would expedite the prosecution of this application, please telephone Ping Hwung at (408) 553-3738.

The Commissioner is hereby authorized to charge any underpayment of fees associated with this communication, including any necessary fees for extensions of time, or credit any overpayment to Deposit Account No. 50-1078, order number 10030938-1.

Respectfully submitted,

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